

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US05/012122

International filing date: 11 April 2005 (11.04.2005)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/561,390
Filing date: 12 April 2004 (12.04.2004)

Date of receipt at the International Bureau: 16 September 2005 (16.09.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse

1365424

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

September 08, 2005

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE.

APPLICATION NUMBER: 60/561,390

FILING DATE: April 12, 2004

RELATED PCT APPLICATION NUMBER: PCT/US05/12122



Certified by

Under Secretary of Commerce
for Intellectual Property
and Director of the United States
Patent and Trademark Office

Please type a plus sign (+) inside this box 

PTO/SB/16 (5-03)
Approved for use through 04/30/2003. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

US PTO
60/561390

INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
STEVEN D. SCOTT J.	KIMMELL GERONDALE	12754 DEON PLACE, GRANADA HILLS, CA 91344-1001 12 RISERO DRIVE, MISSION VIEJO, CA 92692

☐ Additional inventors are being named on the _____ separately numbered sheets attached hereto

TITLE OF THE INVENTION (280 characters max)

MULTI-SITE REMOTELY PRESSURIZED INJECTION SYSTEM

Direct all correspondence to:

CORRESPONDENCE ADDRESS



Customer Number

26822

Place Customer Number
Bar Code here

PATENT TRADEMARK OFFICE

OR

Type Customer Number here



Firm or
Individual Name

WALTER A. HACKLER, Ph.D.

Address

2372 S.E. BRISTOL STREET, SUITE B

Address

City

NEWPORT BEACH

State

CALIFORNIA

ZIP

92660-0755

Country

US

Telephone

(949) 851-5010

Fax

(949) 752-1925

ENCLOSED APPLICATION PARTS (check all that apply)



Specification Number of Pages

7



CD(s), Number



Drawing(s) Number of Sheets

2



Other (specify)

ASSIGNMENT; COVER SHEET



Application Data Sheet. See 37 CFR 1.76

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)



A check or money order is enclosed to cover the filing fees



The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number:

08-0114



Payment by credit card. Form PTO-2038 is attached.

FILING FEE
AMOUNT (\$)

\$160.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.



No.



Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE

TYPED or PRINTED NAME WALTER A. HACKLER

TELEPHONE

(949) 851-5010

Date

04/12/2004

REGISTRATION NO.

27,792

(if appropriate)

Docket Number:

3156P

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

P19LARGE/REV05

MULTI-SITE REMOTELY PRESSURIZED INJECTION SYSTEM

The present invention is generally directed to the administration of a medicament and is more particularly directed to a multi-site injection system for dermal delivery of a medicament.

SUMMARY OF THE INVENTION

10 A multi-site injection system in accordance with the present invention generally includes a shell including a top and a bottom and a plurality of needles protruding from the shell bottom. Each of the needles include a lumen extending through the shell bottom.

15

A membrane is provided and disposed between the shell top and the shell bottom and an inlet is provided for introducing a fluid between the shell top and the shell bottom.

20 A diverter is also provided for selectively directing fluid between the membrane and the shell bottom and between the membrane and the shell top.

The diverter may include a manually operated valve and 25 the system may further include a supply of medicament, preferably botulinum toxin, for introduction between the membrane and the shell bottom.

An inert fluid supply may also be provided for introduction between the membrane and the shell top.

Also in accordance with the present invention, a method
5 of multi-site injection comprises providing a shell between the top and a bottom with bottom having a plurality of needles protruding therefrom with each needle including a lumen therethrough and extending through the shell bottom.

10 The method also includes providing a membrane between the shell top and the shell bottom.

More particularly, in accordance with the present invention, the method includes introducing a medicament
15 between the membrane and the shell bottom and introducing a pressurized fluid between the membrane and the shell top for forcing the medicament through the needle lumens. In this method, the medicament preferably comprises botulinum toxin.

20 BRIEF DESCRIPTION OF THE DRAWINGS

The advantages and features of the present invention will be better understood by the following description when considered in conjunction with the accompanying drawings in
25 which:

Figure 1 is a perspective view of a multi-site injection system in accordance with the present invention generally illustrating a shell having a top and a bottom with a

plurality of needles protruding from the shell bottom. An inlet for introducing fluid between the shell top and bottom is shown along with a diverter;

5 Figure 2 is a cross sectional view of the system shown in Figure 1 more clearly illustrating the shell top, bottom and a membrane disposed between the shell top and the shell bottom along with a diverter valve for selectively directing fluid between the membrane and the shell bottom and between the
10 membrane and the shell top, Figure 2 showing a filling cycle with medication being injected into a reservoir; and

 Figure 3 is a cross sectional view similar to Figure 2 showing the diverter selectively directing fluid between the
15 membrane and top shell during an injection cycle in order to pressurize the reservoir of medicament thereby forcing the medicament through needle lumens; and

 Figure 4 is an enlarged view of the needles illustrating
20 a lumen therethrough for injection of the medicament into the stratum corneum of a users skin (not shown).

DETAILED DESCRIPTION

25 With reference to Figures 1-3, there is shown a multi-site injection system 10 in accordance with the present invention generally including a shell 12 having a top 16 and a bottom 18. A plurality of needles 22 protrude from the shell bottom 18 with each needle 22 including a lumen 24 (see Figure

3156

4) communicating with a reservoir 26 established by a membrane 28 disposed between the shell top 16 and the shell bottom 18.

5 It should be appreciated that the shell, membrane and needles may be made from any suitable material. Preferably, the needles have a gauge of about 28 and a length in the order of 2mm. An inlet 30 including a tube 32 and passageway 34 provide a means for introducing a fluid between the shell top 16 and shell bottom 18.

10

A diverter 38 includes a manually operated valve 40 for selectively directing fluid between the membrane 28 and shell bottom 18 into the reservoir 26.

15 As shown by the arrow 44 during a filling cycle the inlet, or supply line, introduces a medicament, preferably botulinum toxin, into the reservoir by alignment with a dip tube 48 with the passageway 34 for filling of the reservoir 26.

20

Thereafter, the diverter 38 by way of the valve 40 aligns the passageway 34 for introducing a fluid, such as saline solution, between the membrane 28 and the top shell as illustrated by the arrows 52, 54. This provides a pressure
25 above the membrane 28 which forces the medicament from the reservoir 26 through the needle lumens 24 as illustrated by the arrows 58.

Although there has been hereinabove described a specific multi-site remotely pressurized injection system in accordance with the present invention for the purpose of illustrating the manner in which the invention may be used to advantage, it
5 should be appreciated that the invention is not limited thereto. That is, the present invention may suitably comprise, consist of, or consist essentially of the recited elements. Further, the invention illustratively disclosed herein suitably may be practiced in the absence of any element
10 which is not specifically disclosed herein. Accordingly, any and all modifications, variations or equivalent arrangements which may occur to those skilled in the art, should be considered to be within the scope of the present invention as defined in the appended claims.

15

WHAT IS CLAIMED IS:

1. A multi-site injection system comprising:
 - a shell including a top and a bottom;
 - 5 a plurality of needles protruding from the shell bottom, each needle including a lumen extending through the shell bottom;
 - a membrane disposed between the shell top and shell bottom;
 - 10 an inlet for introducing a fluid between the shell top and the shell bottom; and
 - a diverter for selectively directing fluid between the membrane and the shell bottom and between the membrane and the shell top.
- 15 2. The system according to claim 1 wherein said diverter includes a manually operated valve.
- 20 3. The system according to claim 2 further comprising a supply of medicament for introduction between the membrane and the shell bottom.
- 25 4. The system according to claim 3 further comprises a supply of inert fluid for introduction between the membrane and the shell top.
5. The system according to claim 4 wherein said medicament comprises botulinum toxin and said inert fluid comprises a saline solution.

6. A method of multi-site injection comprises:

providing a shell including a top and a bottom, said bottom having a plurality of needles protruding therefrom with
5 each needle including a lumen therethrough and extending through the shell bottom;

providing a membrane between the shell top and the shell bottom;

introducing a medicament between the membrane and
10 the shell bottom; and

introducing a pressurized fluid between the membrane and the shell top for forcing the medicament through the needle lumen.

15 7. The method according to claim 6 wherein said medicament comprises botulinum toxin.

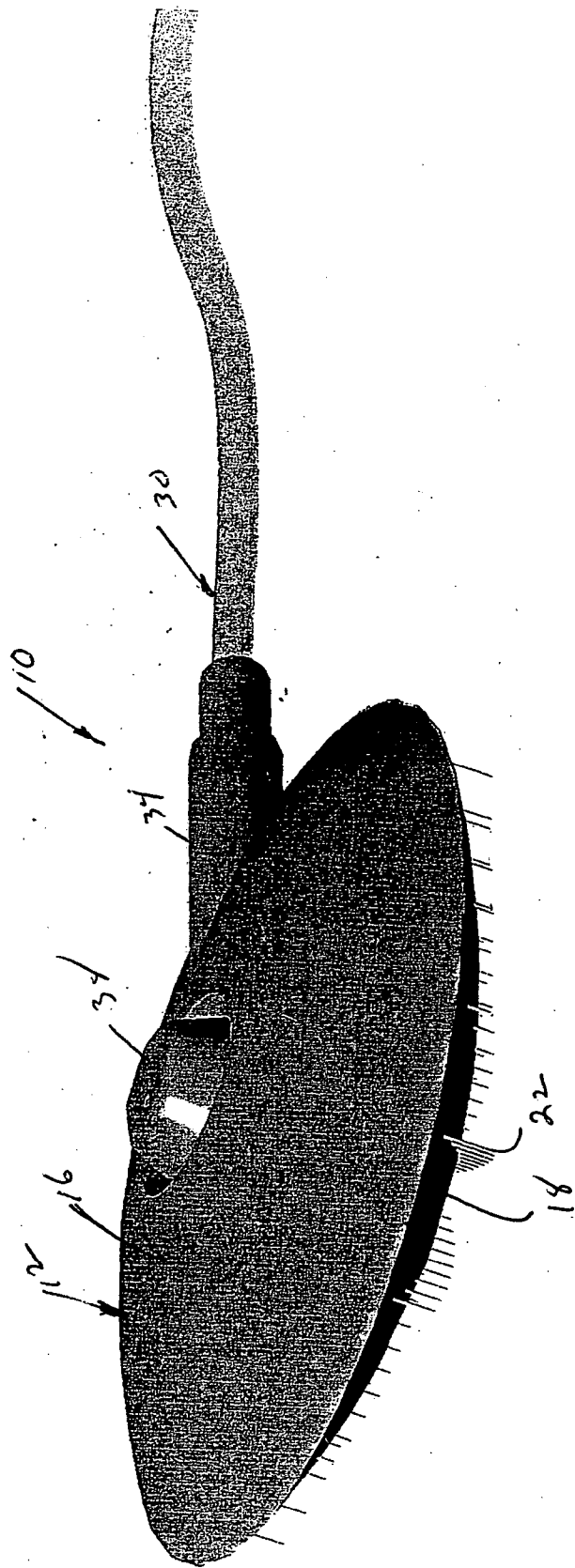
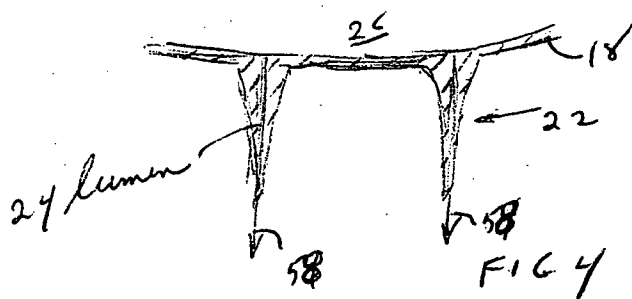
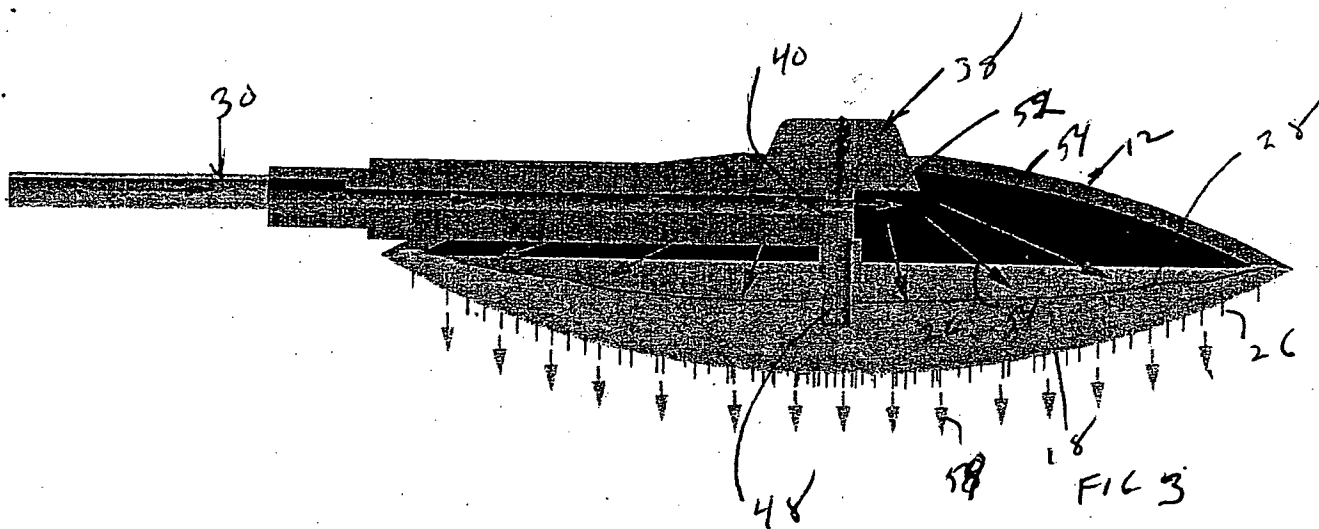
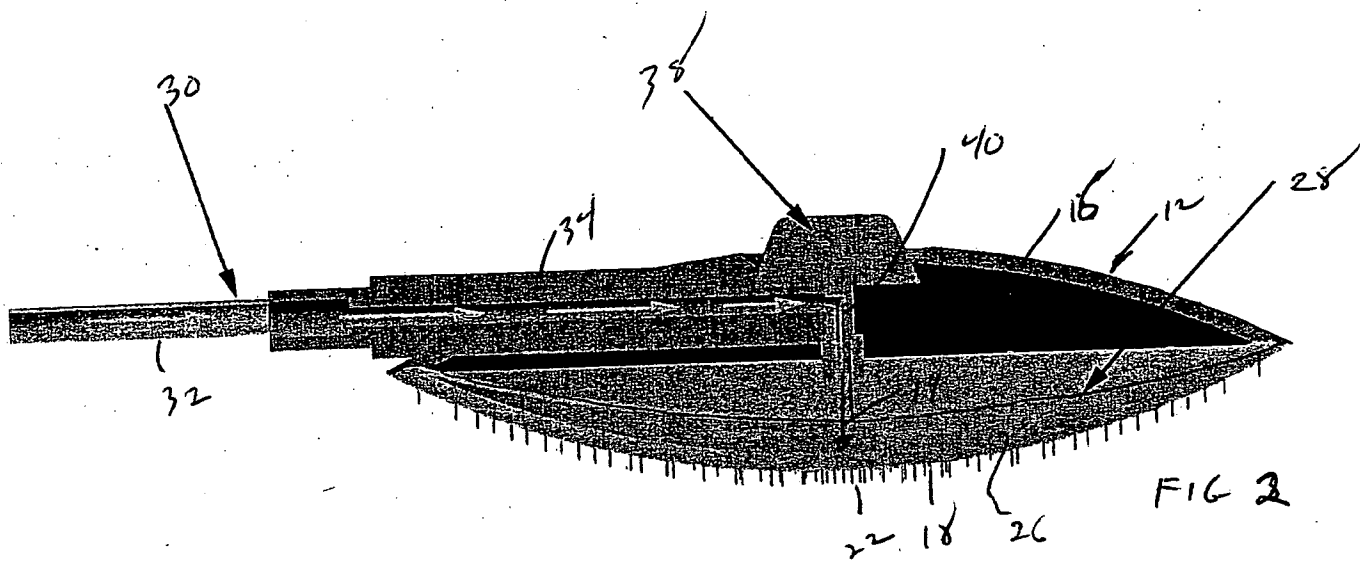


FIG. 1

BEST AVAILABLE COPY



BEST AVAILABLE COPY